

## **REMARKS**

### **I. Status of the Claims**

In a response to the Office Action mailed on March 3, 2010 (the "Office Action"), Applicants respectfully request entry and consideration of the claims provided herein. Claims 1, 2, 4-33 and 38-47 are currently pending in the application. Claims 1, 2, 4, 10, 13, 14, 17-19, 21-27, 29-31, 41, 45 and 46 are rejected and Claims 7-9, 11, 12, 15, 16, 20, 28, 32, 33, 38-40, 42-44 and 47 are currently withdrawn. By way of this response, Claims 1, 5, 6, 32, 33, 38, and 39 have been amended and Claims 4 and 21 has been cancelled.

### **II. Support for the Amendments**

The amendments provided herein do not constitute new matter. Support for the amended claims can be found in the claims and specification as filed including, *inter alia*, page 30, para. 2 to page 33, line 2; and page 49, para. 1-2 of the application as filed. Cancellation of any subject matter herein does not constitute an admission that the subject matter is unpatentable for any reason and Applicants reserve the right to file claims directed to the cancelled subject matter in a continuation or other application. Applicants submit that the amendments submitted herewith place all of the pending claims in condition for allowance.

### **III. Election/Restriction**

The Examiner has maintained the restriction/election requirement set forth in the Office Action by asserting that Groups I-III are not linked by any special technical feature. Specifically, it was noted that Claims 5 and 6 do not depend from Claim 4 and that the elected method of Claim 4 does not require administration of the epitopes of Claims 5 and 6. *See Office Action, pages 3-4.* Applicants thank the Examiner for acknowledging that administration of a MUC1 epitope does not foreclose the additional administration of the epitopes of Claims 5 and 6 and for taking notice that Claims 5 and 6 do not depend from Claim 4. Applicants have incorporated the features of Claim 4 into independent Claim 1, thereby

allowing Claim 5 and 6 to depend from the elected method. Thus, by way of this amendment, Groups I-III are linked by the special technical feature of Claim 4.

#### **IV. Specification**

The Examiner has objected to the disclosure as it refers to references to a hyperlink. Applicants have amended the Specification to delete the hyperlink reference on page, 37, lines 26-27. The hyperlink is also no longer active. Thus, the objection is rendered moot.

#### **V. Rejection Under 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected Claims 13 and 14 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner alleges:

These claims are indefinite because claim 10 from which claim 13 and 14 ultimately depend recite a steroid agent, but claim 13 recites that this steroid agent is non-steroidal. Accordingly, it is unclear and cannot be determined how a steroid agent can also be considered a non-steroidal agent. *Office Action, pages 6-7.*

Applicants respectfully traverse this rejection. Claim 10 refers to an "anti-estrogenic steroid agent" which as described in the Specification is not limited to steroids. See, for example, page 9, paragraph 2, titled "Anti-Hormonal (Anti-Estrogenic Steroid) Therapy" which recites:

An antihormonal therapeutic agent is a chemical agent which reduces the level of estrogen in the body, or which antagonizes estrogen activity. The term "chemical agent" is used to exclude radiation therapy or surgery. Of course, these treatments may be used in addition to the contemplated chemical treatment. The chemical agent may be a biochemical, such as an enzyme or hormone. (*Emphasis added*).

Also see, page 6, last paragraph in the Specification:

By anti-hormonal (anti-estrogenic steroid) therapy is meant therapy which comprises administration of an agent which inhibits an endogenous hormone (a human estrogenic steroid) which, at normal or elevated levels of activity, is a risk factor for breast cancer.

Further anti-hormonal therapy refers to anti-estrogenic steroid therapy (Specification, page 10, lines 3-5) and for the purposes includes treatment with antiestrogens (both steroidol and nonsteroidol), aromatase inhibitors, and/or functionally equivalent compounds. See, e.g., Specification, page 10, paragraphs 3-5.

Thus, from the references to anti-estrogenic steroid agents and therapy described herein and elsewhere in the Specification, one skilled in the art would be taught that an anti-estrogenic steroid agent is an agent that inhibits an estrogenic steroid and encompasses both steroidal and non-steroidal forms.

Accordingly, Applicants respectfully solicit withdrawal of this rejection.

#### **VI. Rejection Under 35 U.S.C. § 112, First Paragraph**

The Examiner has rejected Claim 21 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection is rendered moot by the amendments filed herewith.

#### **VII. Rejections Under 35 U.S.C. § 102**

##### **A. Alhert *et al.***

Claims 1, 2 and 31 are rejected under 35 U.S.C. § 102(a) as being anticipated by Alhert *et al.* J. Clin. Onc., 15(4):1354-1366, 1997 as evidenced by Buzdar *et al.* Clin. Can. Res., 4:527-534, 1998. Specifically, the Examiner alleges:

Alhert et al teach methods comprising administering to a subject with breast cancer standard hormonal agents known to treat breast cancer and an immunogen comprising at least one breast cancer-associated epitope, i.e., an autologous breast tumor cell immunogen to induce an immune response and these agents are administered to subjects in conjunction with each other. Alhert et al also teach methods administering to a subject with metastatic breast cancer a hormonal agent known to treat breast cancer and an immunogen comprising at least one breast cancer-associated epitope, i.e., autologous breast tumor cell immunogen, to induce an immune response (see entire document, e.g., page 1355 and 1361). Accordingly, because Alhert et al teach administration of standard hormonal agents that as evidenced by Buzdar et al inherently are anti-estrogenic agents, in referencing standard hormone therapy Alhert et al inherently teaches administration of anti-estrogenic agents. *Office Action, page 11.*

It is well settled that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (MPEP §2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)) (emphasis added).

Applicants submit that Alhert discloses purified autologous tumor-cell vaccine immunogens (ATV-NDV) derived from non-lytic Newcastle disease virus-infected tumor cells. The claims as amended recite immunogens comprising a MUC1 epitope having one to eight effective tandem repeats of SEQ ID NO:1. Alhert does not describe immunogens with MUC1 epitopes. Because Alhert fails to recite immunogens with MUC1 epitopes, Applicants respectfully request withdrawal of this rejection.

**B. Gilewski *et al.***

Claims 1, 2, 4 and 31 are rejected under 35 U.S.C. § 102(a) as being anticipated by Gilewski *et al.* Clin. Can. Res., 6:1693-1701, 2000 as evidenced by Buzdar *et al.* Clin. Can. Res., 4:527-534, 1998. Specifically, the Examiner alleges:

Gilewski *et al* teach methods comprising administering to breast cancer subjects a hormonal agent known to treat breast cancer and a MUC1 immunogen to induce an immune response to the immunogen and that these agents are administered to subjects in conjugation with each other. (see entire document, e.g., page 1694). Accordingly, because Gilewski *et al* teach administration of hormonal agents that as evidenced by Buzdar *et al* inherently are anti-estrogenic agents, in referencing hormone therapy Gilewski *et al* inherently teaches administration of anti-estrogenic agents. *Office Action, page 12.*

Applicants submit that Gilewski does not disclose immunological agents comprising of a liposome. Instead, Gilewski describes a conjugate that is administered along with a saponin adjuvant, QS-21. Nowhere in the publication is liposome referenced. Thus, Applicants submit that Claims 1, 2, 4 and 31 as amended are not anticipated by Gilweski and, accordingly, respectfully request withdrawal of this rejection.

**C. McCluskie *et al.***

Claims 1, 2, 4, 10, 13, 14, 17-19, 22-27, 29-31, 41, 45 and 46 are rejected under 35 U.S.C. § 102(a) as being anticipated by McCluskie *et al.* U.S. Pat. App. No. 2001/0044416 A1 (2001).

Specifically, the Examiner alleges:

McCluskie *et al* teach methods comprising administering to breast cancer subjects a MUC1 immunogen to induce an immune response to the immunogen, and hormone therapy including tamoxifen alone or in combination with progesterone. McCluskie *et al* teach that the methods can further comprise administering chemotherapeutic agents such as paclitaxel or doxorubicin (see entire document e.g., pages 23 and 24, claims 1 and 6). *Office Action, page 12.*

Applicants respectfully traverse and submit that McCluskie does not disclose the method of treating breast cancer comprising each of the components set forth in the claims herein. It is respectfully pointed out that McCluskie simply does not specifically disclose a method for treating breast cancer with a first amount of anti-estrogenic steroid agent and a second amount of an immunological agent having an immunogen of a MUC1 epitope and a liposome.

Applicants respectfully point out that “every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim.” *Gechter v. Davidson*, 116 F.3d 1454, 1457 (Fed. Cir. 1997); *see also* MPEP §2131. “[P]icking and choosing [from a single reference]...has no place in the making of a 102, anticipation rejection.” *In re Arkley*, 455 F/2d 586, 587-588 (CCPA 1972). With regard to the instant case, Applicants respectfully submit that McCluskie does not disclose every limitation of the instant claims and thus, does not anticipate the instant claims.

To allege that a method claimed herein is anticipated by McCluskie, the Examiner relies on the treatment of breast cancer claimed herein from a long list of cancers for treatment provided in McCluskie including basal cell carcinoma, bladder cancer, bone cancer, brain and CNS cancer, breast cancer, cervical cancer, colon and rectum cancer, connective tissue cancer, esophageal cancer, eye cancer, kidney cancer, larynx cancer, liver cancer, lung cancer, Hodgkin's lymphoma, Non-Hodgkin's lymphoma, melanoma, myeloma, leukemia, oral cavity cancer (e.g., lip, tongue, mouth, and pharynx), ovarian cancer, pancreatic cancer, prostate cancer, rhabdomyosarcoma, skin cancer, stomach cancer, testicular cancer, and uterine cancer. *See McCluskie, para. [0153]*.

Likewise for immunological agents, McCluskie lists over 25 different cancer vaccines that can be used in conjunction with a Th2 immunostimulatory nucleic acid including EGF, Anti-idiotypic cancer vaccines, Gp75 antigen, GMK melanoma vaccine, MGv ganglioside conjugate vaccine, Her2/neu, Ovarex, M-Vax, O-Vax, L-Vax, STn-KHL theratope, BLP25 (MUC-1), liposomal idiotype vaccine, Melacine, peptide antigen vaccines, toxin/antigen vaccines, MVA-based vaccine and PACIS to name a few. *McCluskie, para. [0152]*. This is in addition to the large variety of antibody-based anti-cancer

immunotherapies described on pages 21-23 of McCluskie that can be suitable with Th2 immunostimulatory nucleic acids.

Finally, regarding the disclosure of anti-estrogenic steroid agents such as paclitaxel or doxorubicin in McCluskie, Applicants submit that McCluskie discloses a laundry list of other chemotherapeutic agents for combination treatment *with Th2 immunostimulatory nucleic acids*, not immunogens as described in the instant claims. *See McCluskie, para. [0151]*. As for progesterone and tamoxifen, the sole disclosure in McCluskie states that "Hormone replacement therapy includes tamoxifen alone or in combination with progesterone." *McCluskie, para. [0152]*.<sup>1</sup> Additionally, McCluskie does not disclose that these compounds are to be used with cancer vaccines but instead, to be used with Th2 immunostimulatory nucleic acids.

As illustrated above, McCluskie lists a huge variety of elements that can be used with Th2 immunostimulatory nucleic acids. To arrive at the claimed methods of treating breast cancer in the instant case, one would have to (1) selectively choose from the large number antibody-based and other cancer immunotherapies, an immunogenic agent comprising a MUC1 epitope; (2) an anti-estrogenic steroid agents from a broad-based number of chemotherapeutic agents; and finally (3) a treatment for a breast cancer selected from list of different cancers. This is notwithstanding the fact that the immunotherapies and chemotherapies are to be used with Th2 immunostimulatory nucleic acids and not in combination with each other.

As the Federal Circuit's predecessor court has noted above in *In re Arkley*, this is improper "picking and choosing" of elements from various portions of the McCluskie reference to arrive at the methods claimed herein. As a result, the Examiner is relying on a reconstruction of the claims from a large number of factors.

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<sup>1</sup> Applicants further point out that McCluskie describes the use of these compounds for hormone replacement therapy. The instant case distinguishes hormonal therapy with hormone replacement therapy. *See, e.g., Specification, page 10, lines 6-10.*

Finally, Applicants respectfully point out that for a reference to be anticipatory, it must also "enable one of ordinary skill in the art to make the invention without undue experimentation." *In re Gleave*, 650 F.3d 1331, 1134 (Fed. Cir. 2009), see also *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed.Cir.2008); *In re LeGrice*, 49 C.C.P.A. 1124, 301 F.2d 929, 940-44 (1962). Here, even if one were able to select elements from the McCluskie to arrive at the claimed methods, McCluskie still does not disclose how to use the elements together into a workable form for treating breast cancer. Instead as mentioned previously McCluskie discloses compositions and uses for Th2 immunostimulatory nucleic acids. One would perform undue experimentation to make the invention of the claimed methods of the instant case.

Accordingly, for these reasons presented herein, Applicants respectfully request that this rejection be withdrawn.

#### **VIII. Rejections Under 35 U.S.C. § 103**

##### **A. Alhert *et al.* & Buzdar *et al.***

Claims 1, 2, 10 13, 14, 17-19, 27, 29-31, 41, 45 and 46 are rejected under 35 U.S.C. § 103(a) as being rendered obvious by Alhert *et al.* J. Clin. Onc., 15(4):1354-1366, 1997 in view of Buzdar *et al.* Clin. Can. Res., 4:527-534, 1998.

Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (A) Ascertaining the scope and content of the prior art; and
- (B) Ascertaining the differences between the claimed invention and the prior art; and
- (C) Resolving the level of ordinary skill in the pertinent art.

*See Graham v. John Deere Co.*, 383 U.S. 1, (1966); *see also* M.P.E.P. § 2141(II).

Once these factual inquiries have been completed, the Examiner must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. According to the M.P.E.P., "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." M.P.E.P. § 2141(III). Moreover, the result of any obviousness inquiry must, generally, provide a predictable result or have an expectation of success. *See id.*

Here, the Examiner alleges:

Alhert et al teach what is set forth in the above rejection of the claims under 102(b). While Alhert et al teaches administering an autologous tumor cell immunogen and hormonal therapy, along with adjuvant chemotherapy and radiation, Alhert et al does not expressly teach administering the hormonal therapies tamoxifen, progesterone or an anti-progestin to breast cancer subjects. *Office Action, page 14.*

To overcome the deficiencies of Alhert, the Examiner cites Budzar and alleges it teaches:

Budzar et al teach [that] administering tamoxifen, progesterone or an anti-progestin to breast cancer subjects was known in the art. *Office Action, page 14.*

Given these teachings, the Examiner alleges,

[I]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer tamoxifen and progesterone and/or an anti-progestin along with the autologous tumor cell immunogen of Alhert et al. *Office Action, page 14.*

The claims as amended recite immunological agents having immunogens with MUC1 epitopes. As Applicants have noted above, Alhert does not describe immunogens with MUC1 epitopes, only autologous tumor cell immunogens as the Examiner has submitted. Because Alhert as well as Budzar do not describe immunogens with MUC1 epitopes nor teach or suggest these epitopes in the pending claims, Applicants respectfully traverse the allegation that the combination of these references renders the pending claims obvious or that a person of ordinary skill in the art would have had a reason to combine the cited references. A *prima facie* case of obviousness is therefore not established. Accordingly, Applicants respectfully solicit withdrawal of this rejection.

**B. Alhert et al. & Nabholtz et al.**



Claims 1 and 22-26 are rejected under 35 U.S.C. § 103(a) as being rendered obvious by Alhert *et al.* J. Clin. Onc., 15(4):1354-1366, 1997 in view of Nabholtz *et al.* Onc., 6(S3) 5-12. 2001. Specifically, the Examiner sets forth that:

While Alhert *et al.* teaches administering an autologous tumor cell immunogen and hormonal therapy, along with adjuvant chemotherapy and radiation, Alhert *et al.* does not expressly teach that administering doxorubicin or paclitaxel as chemotherapy to breast cancer subjects. *Office Action, page 15.*

To overcome the deficiencies of Alhert, the Examiner cites Nabholtz and alleges it teaches:

Nabholtz *et al.* teach [that] administering doxorubicin or paclitaxel as chemotherapy to breast cancer subjects was known in the art. *Office Action, page 15.*

Given these teachings, the Examiner alleges,

[I]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer doxorubicin and/or paclitaxel along with the autologous tumor cell immunogen and hormone therapy of Alhert *et al.* *Office Action, page 15.*

The claims as amended recite immunological agents having immunogens with MUC1 epitopes. As Applicants have noted above, Alhert does not describe immunogens with MUC1 epitopes, only autologous tumor cell immunogens as the Examiner has submitted. Because Alhert as well as Nabholtz do not describe immunogens with MUC1 epitopes nor teach or suggest these epitopes in the pending claims, Applicants respectfully traverse the allegation that the combination of these references renders the pending claims obvious or that a person of ordinary skill in the art would have had a reason to combine the cited references. A *prima facie* case of obviousness is therefore not established. Accordingly, Applicants respectfully solicit withdrawal of this rejection.

**C. Gilewski *et al.* & Buzdar *et al.***

Claims 1, 2, 4, 10, 13, 14, 17-19, 22-27, 29-31, 41, 45 and 46 are rejected under 35 U.S.C. § 103(a) as being rendered obvious by Gilewski *et al.* Clin. Can. Res., 6:1693-1701, 2000 in view of Buzdar *et al.* Clin. Can. Res., 4:527-534, 1998. Specifically, the Examiner alleges that:

While Gilewski *et al.* teaches administering a MUC1 immunogen and hormonal therapy, Gilewski *et al.* does not expressly teach administering the hormonal therapies tamoxifen, progesterone or an anti-progestin to breast cancer subjects. *Office Action, page 16.*

To overcome the deficiencies of Gilewski, the Examiner cites Budzar and alleges it teaches:

Budzar et al teach [that] administering tamoxifen, progesterone or an anti-progestin to breast cancer subjects was known in the art. *Office Action, page 16.*

Given these teachings, the Examiner alleges,

[I]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer tamoxifen and progesterone and/or an anti-progestin along with the MUC1 immunogen of Gilewski et al. *Office Action, page 17.*

The claims as amended recite immunological agents comprising of a liposome. As Applicants have noted above, Gilewski does not reference liposome formulations but rather a conjugate that is administered along with a saponin adjuvant, QS-21. Further, Gilewski as well as Budzar do not teach or suggest immunological agents having a liposome. Applicants respectfully traverse the allegation that the combination of these references renders the pending claims obvious or that a person of ordinary skill in the art would have had a reason to combine the cited references and submit that *prima facie* case of obviousness is therefore not established. Accordingly, Applicants respectfully solicit withdrawal of this rejection.

**D. Gilewski et al. & Nabholtz et al.**

Claims 1 and 22-26 are rejected under 35 U.S.C. § 103(a) as being rendered obvious by Gilewski et al. Clin. Can. Res., 6:1693-1701, 2000 in view of Nabholtz et al. Onc., 6(S3) 5-12. 2001.

Specifically, the Examiner alleges that:

While Gilewski et al teaches administering a MUC1 immunogen and hormonal therapy, Gilewski et al does not expressly teach administering doxorubicin or paclitaxel to breast cancer subjects. *Office Action, page 18.*

To overcome the deficiencies of Gilewski, the Examiner cites Nabholtz and alleges it teaches:

Nabholtz et al teach [that] administering doxorubicin or paclitaxel as chemotherapy to breast cancer subjects was known in the art. *Office Action, page 18.*

Given these teachings, the Examiner alleges,

[I]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer doxorubicin or paclitaxel along with the MUC1 immunogen and hormone therapy of Gilewski et al. *Office Action, page 18.*

The claims as amended recite immunological agents comprising of a liposome. As Applicants have noted above, Gilewski does not reference liposome formulations but rather a conjugate that is

administered along with a saponin adjuvant, QS-21. Further, Gilewski as well as Nabholtz do not teach or suggest immunological agents having a liposome. Applicants respectfully traverse the allegation that the combination of these references renders the pending claims obvious or that a person of ordinary skill in the art would have had a reason to combine the cited references and submit that *prima facie* case of obviousness is therefore not established. Accordingly, Applicants respectfully solicit withdrawal of this rejection.

**E. McCluskie *et al.* & Buzdar *et al.***

Claims 1, 2, 10 13, 14, 17-19, 27, 29-31, 41, 45 and 46 are rejected under 35 U.S.C. § 103(a) as being rendered obvious by McCluskie *et al.* U.S. Pat. App. No. 2001/0044416 A1 (2001) in view of Buzdar *et al.* Clin. Can. Res., 4:527-534, 1998. Specifically, the Examiner alleges that:

While McCluskie *et al.* teach administering a MUC1 immunogen and the hormone therapy tamoxifen, McCluskie does not expressly teach administering an anti-progestin to breast cancer subjects. *Office Action, page 19.*

To overcome the deficiencies of McCluskie, the Examiner cites Budzar and alleges it teaches: Budzar *et al.* teach [that] administering an anti-progestin to breast cancer subjects was known in the art. *Office Action, page 19.*

Given these teachings, the Examiner alleges,

[I]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a MUC1 immunogen and a tamoxifen and an anti-progestin. *Office Action, page 19.*

Applicants respectfully traverse and submit that McCluskie does not disclose nor teaches administering a MUC1 immunogen and a hormone therapy such as tamoxifen or progesterone. Specifically, McCluskie states:

Th2 immunostimulatory nucleic acids may also be administered with cancer vaccines selected from the group consisting of EGF, Anti-idiotypic cancer vaccines, Gp75 antigen, GMK melanoma vaccine, MGv ganglioside conjugate vaccine, Her2/neu, Ovarex, M-Vax, O-Vax, L-Vax, STn-KHL theratope, BLP25 (MUC-1), liposomal idiotypic vaccine, Melacine, peptide antigen vaccines, toxin/antigen vaccines, MVA-based vaccine, PACIS, BCG vaccine, TA-HPV, TA-CIN, DISC-virus and ImmuCyst/TheraCys. Biological response modifiers include interferon, and lymphokines such as IL-2. Hormone replacement therapy includes tamoxifen alone or in combination with progesterone. *McCluskie, para [0152].*

The above passage in no way teaches or suggests that the cancer vaccines are used in combination with the hormone replacement therapy agents. Rather, the disclosure depicts that one could use either a cancer vaccines or hormone replacement therapy along with Th2 immunostimulatory nucleic acids. Moreover, this is also the only passage reciting hormones and cancer vaccines with MUC1 epitopes.

Applicants wish to further point out that McCluskie describes the use of these tamoxifen and/or progesterone for hormone replacement therapy. The instant case distinguishes hormonal therapy with hormone replacement therapy and the compounds used for hormonal therapy are intended for a different purpose than use in a hormone replacement therapy. See, *e.g.*, Specification, page 10, lines 6-10. As such, McCluskie neither teaches nor suggests the use of any compounds for hormonal therapy as delineated in the Specification of the instant case.

Furthermore, as Applicants have pointed out in the § 102 discussion herein, McCluskie lists a huge variety of elements in its disclosure that can be used with Th2 immunostimulatory nucleic acids. To arrive at the claimed methods of treating breast cancer in the instant case, one of ordinary skill in the art would have to, for example, selectively choose from the large number antibody-based and other cancer immunotherapies, an immunogenic agent comprising a MUC1 epitope from pages 21-24 of McCluskie. McCluskie gives no guidance into pointing out and selecting an immunogenic agent comprising a MUC1 epitope.

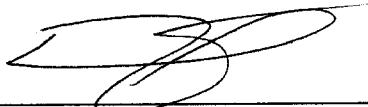
Accordingly, for the reasons described herein, Applicants assert that a *prima facie* case of obviousness is not established. In light of the foregoing arguments, Applicants respectfully request withdrawal of this rejection.

**CONCLUSION**

Applicants submit that this response fully addresses the Office Action mailed March 3, 2010. Applicants believe that for the reasons set forth herein the pending claims are in condition for allowance and early and favorable consideration is respectfully requested. Further, none of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

Should the Examiner have any questions or concerns, the Examiner is encouraged to contact the undersigned attorney at (858) 350-2306.

Respectfully submitted,  
WILSON SONSINI GOODRICH & ROSATI  
Professional Corporation



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